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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,158	01/04/2002	Jan Weber	12013/59401	1766

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/035,158

Applicant(s)

WEBER ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/10/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 13-16, 18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089 or Mandrusov et al US Patent 6,660,034 B1.

Hillstead discloses a system comprising: an expandable stent (32), a compliant sheath (40) and an expandable balloon (34). The stent is in contact and crimped over the sheath (see Fig. 4) and the sheath is made of Latex (see col. 4, lines 36-37). The sheath comprises a tube (see Fig. 2) and the tube comprises a length that is greater than the length of the stent (see Fig. 3). Finally, the tube is attached to the balloon at the proximal and distal ends (see Fig. 9 and col. 5, lines 43-45).

Sahatjian et al discloses a delivery system comprising a catheter, a balloon and a stent. The stent comprises an inner surface having a liner made of hydrogel. The hydrogel is capable of having a therapeutic agent in order to reduce or prevent clotting and/or restenosis at the stent site (see col. 1, lines -55-67 and col. 2, lines 1-31).

Mandrusov et al discloses a stent having a liner and/or a sheath in order to deliver therapeutic substances downstream in the lumen.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material properties of the stent of the Hillstead or Mandrusov et al reference by adding a coating (with drugs) to the stent in order to reduce or prevent clotting and/or restenosis at the stent site.

Regarding claims 7, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the end of the compliant sheath of the Hillstead reference because the applicant has not disclosed that by closing about at least one of a distal end of the sheath provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the two ends of the sheath open (as discloses by the applicant in paragraph 27) because the sheath will greatly reduces, if not completely obviates, the winging effect frequently observed in different balloon catheters (see col. 4, lines 64-68 and col. 5, lines 1-4).

Therefore, it would have been an obvious matter of design choice to modify Hillstead reference to obtain the invention as specified in claim 7.

Regarding claim 18, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the sheath of the Hillstead reference because the applicant has not disclosed that by using a transparent sheath provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the latex sleeve of the Hillstead reference because the latex sleeve will perform the required task that is the expansion of the stent.

Therefore, it would have been an obvious matter of design choice to modify Hillstead reference to obtain the invention as specified in claim 18.

Regarding claim 23, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the delivery system of the Hillstead reference by adding one or more radiopaque markers to the delivery system because Applicant has not disclosed that the radiopaque markings provides an advantage, is used for a particular purpose, solves a stated problem or is a critical part of the invention. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the delivery system used in the Hillstead reference.

Therefore, it would have been an obvious matter of design choice to modify the Hillstead reference to obtain the invention as specified in claim 23.

Regarding claim 24, see Fig. 9.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089 or Mandrusov et al US Patent 6,660,034 B1 as applied to claim 1 above, and further in view of Hyde et al EP 0553960A1.

Hillstead as modify by Sahatjian discloses a sheath fixedly attached to the balloon at the proximal and distal ends of the balloon. Hillstead discloses a non-compliant balloon ((38) attached to a compliant sleeve (40) at the proximal and distal ends of each structure (see col. 4, lines 42-46 and Fig. 9). However, Hillstead is silent of how the two structures are attached to each other (does not disclose an adhesive).

Hyde et al discloses a balloon connected to the rest of the catheter by an adhesive or by any mechanical means for the purpose of sealingly connects the two structures together (see col. 6, lines 13-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fixation method of the Hillstead reference with the adhesive of the Hyde et al reference in order to sealingly connects the two structures together.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead US Patent 5,116,318 in view of Sahatjian et al US Patent 5,843,089 or Mandrusov et al US Patent 6,660,034 B1 as applied to claim 1 above, and further in view Osborn US Patent 5,409,495.

Hillstead as modify by Sahatjian discloses the invention substantially as claimed. However, Hillstead as modify by Sahatjian do not disclose a lubricant between the balloon and the sheath for the purpose of reducing fiction between structures.

Osborn discloses a catheter having a balloon and a stent. The balloon has a plurality of layers (see Fig. 2) and lubricant. The lubricants are placed between all the interfacing surfaces of the layers (see col. 5, lines 20-25) for the purpose of reducing additional friction and enhance the uniform expansion of the balloon (see col. 5, lines 25-31)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Hillstead reference with the lubricant solution of the Osborn reference in order to reduce the fiction between the structures and enhance the uniform expansion of the balloon.

***Response to Arguments***

Applicant's arguments filed 12/10/04 have been fully considered but they are not persuasive.

The Applicant's representative discloses that none of the references suggest or disclose the claimed subject matter shown in claims 1-18 and the combination of the references is not proper. For example, none of the cited references employ a sheath and a coated stent.

The Examiner disagrees with the Applicant's representative point of view. Hillstead clearly discloses a delivery system comprising an expandable stent, a compliant sheath and an expandable balloon. However, the only thing that it does not show is the coated stent. It is well known in the art the use of different coats to address different conditions. Therefore, it will be obvious to one ordinary skill in the art to interchange the Hillstead stent with a coated stent (e.g. Sahatjian et al or Mandrusov et al) in order to treat a specific condition. For the above reason, the Examiner believes that the previous rejections are proper.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alvin J Stewart  
Primary Examiner  
Art Unit 3738

  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**

March 3, 2005.